SUBMISSION OF RALPH F. IVES
ON BEHALF OF
THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION
TO
THE COMMITTEE ON SECTION 301
JUNE 17, 2019

Introduction

About AdvaMed

The Advanced Medical Technology Association (AdvaMed), with headquarters in Washington D.C., represents over 400 manufacturers of the full range of medical technology – cardiovascular and orthopedic implants, *in vitro* diagnostics, surgical devices, and diagnostic equipment. These technologies, protect, improve and save patients' and care providers' lives around the world. While AdvaMed represents large well-known manufacturers, about 75 percent of our members are America-based small and medium size enterprises.

The U.S. medical device industry is spread throughout all 50 states, with 13,699 facilities. We are directly responsible for over 500,000 high paying American jobs and an estimated total of 2 million jobs (direct and indirect) − and generating over $150 billion annually in direct economic output.

AdvaMed Request

AdvaMed shares the Administration's opposition to Chinese policies that discriminate against U.S. firms. We are also concerned that China could implement the goals of its "Made in China: 2025" policy in a way that leads to additional or strengthened discriminatory practices.

We very much appreciate that the U.S. Trade Representative (USTR) removed approximately $2 billion of medical technology products from its proposed Section 301 list on which an additional 25 percent tariff was imposed on July 6, 2018. We also appreciate that the value of medical technology on the lists enacted on August 23, 2018 and September 24, 2018 list were modest. However, over $836 million of medical technology products remain on the July 6, 2018 list (Annex 1). In addition, component products that are not identified as medical technology (e.g., circuit boards, disk drives, motor parts,) are included in the USTR lists, which can increase the cost of manufacturing certain medical products (Annex 4). Finally, despite the USTR's welcomed exclusion for "select medical

goods," the value of products classified in the harmonized tariff schedule (HTS) as medical devices on the proposed List 4 totals over $1.3 billion (Annex 3).

We ask that: (1) all increased tariffs on HTS codes for medical technology products (as listed in Annex 1 and Annex 2) be removed; (2) no additional tariffs be imposed on the medical products listed in in Annex 3, including HTS numbers: 3926.90.99.10; 3926.90.9990; 4015.19.05.50; 6307.90.60; 6307.90.68; and 6307.90.89.10; 8528.52.00.00; and 9027.90.20.00. In addition, we ask that the impact of increasing tariffs on the component products listed in Annex 4 be recognized and those tariffs not be increased, including 8517.62.0900.

We make this request for the following reasons:

- U.S. trade retaliation and sanctions measures historically have not included medical products due to humanitarian reasons;
- the FRN clearly recognizes the sensitivity of medical goods by indicating the exclusion of "select medical goods," which your include all medical technologies;
- the inadvertent impact would be inconsistent with the President's objectives for balanced trade and of targeting products included in "Made in China: 2025";
- a large share of the imports on the list are components and semi-finished products, which are used by our manufacturers to make products in the United States that are competitive in a global market;
- our industry enjoys a nearly balanced trade relationship with China;
- U.S. tariffs would leave the highly regulated medical technology industry particularly vulnerable to Chinese nontariff measures;
- the import tax has the potential to disrupt some patient access;
- costs are difficult to shift because of multi-year contracts;
- our industry did not participate in the Section 301 process and was not included in the Report.

If tit-for-tat retaliation continues, the Administration's objectives for a strong domestic medical technology industry will be undermined. We ask the Administration to consider this adverse impact and to remove all medical technology products from its retaliation lists.

We have provided USTR lists of key issues we have requested be included in the negotiations – discriminatory and non-reciprocal measures by Chinese authorities. These measures involve regulatory and payment policies, which if not corrected or even exacerbated could increase the U.S. trade deficit with China.

<u>The U.S. Medical Technology Industry</u>

The medical technology industry is an American success story. Many of the medical devices and diagnostics on the market today trace their origins to U.S. inventors. Over the technology life cycle, the U.S. industry remains the leading creator of innovation in the global market. This history of innovation ranges from mature, staples of healthcare that are used in almost every patient interaction to rapidly developing advanced medical devices. The average lifespan of a new medical device is about 18-24 months – e.g., an

improvement in a pacemaker today is likely to be overtaken by another breakthrough by 2021.

The U.S. industry has been historically competitive globally, and we remain so. The U.S. industry is one of the few manufacturing and technology industries that has consistently maintained a trade surplus. U.S. exports of medical technology to the world totaled $52.5 billion in 2017, and imports were $51.4 billion – for a surplus of $1.1 billion.

But over time that surplus has diminished. In 2007, the United States exported $34.7 billion and imported $29.1 billion of medical devices – for a surplus of $5.5 billion. The ratio of the surplus to total medical technology trade was nine percent in 2007 compared to one percent in 2017 – indicating a decreasing relative surplus. This change is a result of competitive pressures in other countries – as business people in other markets expand their own medical technology industries – but also because of government measures that favor local firms – e.g., "localization" preferences, including in China.

Impact of USTR's Proposed Actions

USTR's Proposed Actions

In its announcement of April 4, 2018, USTR proposed to impose additional 25 percent tariffs on $50 billion of U.S. imports from China. We estimated that the imposition of an additional 25 percent duties would have impacted at least $3 billion of medical devices and diagnostics, and related components, entering the United States from China. While we appreciated that about $2 billion were removed, we regret that any medical technology was retained on the final list, as these products are used to treat patients. Also, including medical products on the USTR list – with the exception of pharmaceuticals – encouraged China to add medical technology to its lists.

The USTR list of May 17, 2019 includes up to $1.3 billion of medical devices on which a 25 percent tariff will be added. We oppose these additional tariffs on these products. These products are largely used as consumables in the U.S. healthcare setting, and they would likely result in added costs to the health care system – either manufacturers, patients, providers, or insurers.

Adverse Impact on US Competitiveness

The U.S. medical technology industry is the most innovative and competitive in the world. There are many reasons for this leadership – including our decades of advancement, the high percent of revenue devoted to R&D, efficient supply-chain sourcing, and USG support for leveling the playing field around the world. Another key factor is the industry's consistently strong espousal of open markets – in the United States and in other countries. These factors combine to allow U.S. firms to manufacture the best medical technology for patients in the most efficient way, to grow our industry in the United States, and to hire more American workers.

Rising healthcare costs around the world are putting pressure on governments to cut costs, including in the United States. While we have evidence demonstrating that medical technology can help alleviate cost pressures over time, downward pressures on prices continue – including through the use of price controls in some countries – such as maximum sales prices in Chinese provinces. The U.S. industry must be efficient to thrive.

Increasing our supply-chain costs through higher tariffs would exacerbate our competitiveness problem – with China, Europe, Japan, and many others. AdvaMed member companies source components and semi-finished products from all over the world, including China, to complete the manufacturing process of medical technologies here at home for domestic use or export. We cannot accurately calculate the final cost impact of higher tariffs, as the initial tariff hike reverberates and escalates through the various levels of the supply chain. That is, the tariff increase of 25 percent in the imported component could end up being some multiple of that amount as it is used in intermediate products for resale to the next level of processing and on to the final product.

Shifting the source of inputs for finished medical technologies also involves costs. FDA has regulations affecting changes to input used in manufacturing medical technology. Depending on the risk classification of the product and the use of the component being changed, FDA may require a supplemental submission to the FDA. If this were to occur, changes in sourcing could lead to delays of well over several months to 18 months , as this would require identifying a suitable alternative, notifying FDA, inspecting and validating the specific manufacturing process (e.g., installation, performance, operations), and submitting supplemental registration data. Even if a company believes its product with a new component would not need specific FDA approval, the firm would still be required to use resources to validate that the component from the new source meets specifications, which can also take several months. These stringent standards ensure safety and quality of care but also add significant supply chain complexity and inflexibility with respect to alternative manufacturing locations, let alone countries of origin.

The tariff increase acts as a tax on our members. The president and Congress again suspended the 2.5 percent device tax on revenue earned from sales of medical technology in the United States. The reason this suspension enjoyed overwhelming bipartisan support was because there was clear recognition that this tax undermined U.S. competitiveness and costs U.S. jobs. For some AdvaMed members, the effect of the tariff increases has more than offset gains from suspension of the medical device tax. For those manufacturers, future R&D spending is likely to be cut if the tariffs remain – adversely impacting U.S. competitiveness to pioneer the next generation of life-saving diagnostics and therapies. U.S. jobs would likely be lost, and in some instances, entire product supply options will be limited.

Finally, if the USTR objective in its retaliation process were to try to avoid raising input costs for U.S. industry and, instead, to focus on finished products coming from China, that appears to be very difficult to do. We cannot accurately calculate the relative shares of components versus finished medical technology imported from China. The HTS frequently combines components and finished products, making it difficult to estimate the relative value of each. Our members identified over 90 **non**-medical technology HTS codes for

parts and components on the USTR list that are used in their medical technology products. Our rough estimate is that over 60 percent of the medical technology products on USTR's list include components and semi-finished products used to manufacture finished products in the United States. However, the actual figure could be different.

Inconsistent with USTR Objectives

The Administration's broad objective for bilateral trade with China is to substantially reduce the U.S. trade deficit. In addition, Ambassador Lighthizer has been clear that the USTR retaliation list is intended to target products from those industries identified in the "Made in China:2025" initiative. We recognize that high-end medical technology products are included in China's plan.

Increasing import tariffs on the medical technology products on the USTR lists is not consistent with reducing the trade deficit in our industry. The United States enjoys a roughly balanced trade with China for medical devices and diagnostics. This reciprocal trade relationship in our industry should mean that including these products on the lists is contrary to the Administration's trade deficit objective – i.e., if a trade deficit requires corrective measures, no action should be necessary when trade is balanced.

USTR action could undercut our sales in China. Our members have enjoyed a vibrant growth of trade with China, which imports about 70 percent of its total use of medical technology. China's consumption of medical technology quadrupled during the past decade. U.S. medical technology exports to China have grown every year and exceeded $4.7 billion in 2017; imports from China were about $5 billion. The Chinese industry has also grown rapidly during this period. U.S. firms still have a substantial advantage over Chinese companies when it comes to R&D, manufacturing, and export of high-value medical technology. Chinese patients also strongly prefer foreign brands.

In addition, USTR action could adversely affect U.S. medical technology companies' participation in China's plan to vastly improve healthcare. There are significant opportunities for U.S. medical technology under "Healthy China 2030," which lays out several ambitious public health goals in addition to addressing major demographic shifts and increases in the incidence of non-communicable diseases. This plan is somewhat at odds with "Made in China: 2025," in that China will continue to rely heavily on foreign medical technology in the years ahead to meet growing demand and achieve these public health goals. We need the USG to contribute to making the U.S. industry more competitive, not less, so that our industry can contribute to fulfilling this critical healthcare need and expand U.S. sales in China.

It is also not possible for USTR to accurately target "Made in China: 2025" products because of the limitations of the HTS. The antiquated HTS codes cannot differentiate among the many categories of medical technology products. The HTS was developed in the 1980s − before most medical technology on the market today was invented. The World Health Organization reports that there are over 22,000 generic groups of medical technologies and 2 million types of products. The HTS has only about 120 lines for medical devices and diagnostics, which is clearly inadequate to target types of products.

In addition, the USTR list does not, and cannot, distinguish between the "new" types of medical technology China has specifically targeted in "Made in China: 2025" from the products that have been on the market for years. China has identified "new" high-end medical technology," including:

- medical imaging equipment including MRI, CT, PET-CT, integrated PET-MRI and other new imaging equipment;
- clinical laboratory equipment including molecular diagnostic equipment, automated microbial detection systems, high resolution optical imaging systems;
- advanced treatment equipment such as image-guided radiotherapy equipment, high-definition electronic endoscopes, high-definition confocal endomicroscopy; and
- rehabilitation and medical monitoring devices (including wearable devices).

We estimate that the majority of medical technology products on the USTR lists are not even the categories identified by the Chinese for "Made in China: 2025." The USTR algorithm seems to be aggregating a wide range of the medical technology HTS codes and assuming they are included in the "Made in China: 2025" plan.

U.S. medical technology investment in China is important for our competitiveness with China and globally. Despite the challenges we identified, our members have invested in China, as they have in other countries. The reasons for overseas investments vary but are usually aimed at providing patient access to medical devices and diagnostics in the most timely and affordable means possible, as well as to remain competitive. Achieving these objectives often means that our members' investments need to be located close to patients and supply chains. For example, most U.S. medical technology firms' investments in China are done to supply the Chinese and surrounding markets. Some of that investment is also to manufacture components for medical technology products, including those finished in the United States. A few members ship finished products from China to the United States to respond to demand, which comes primarily from U.S. hospitals that could otherwise not afford the more expensive equipment.
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While our members have experienced a vibrant commercial relationship with China, we recognize the competitive threat from China. Analysis by the International Trade Commission shows that the medical technology industry in China (represented by both Chinese and foreign companies) appears to be moving up the value chain. This increase includes: (1) capital equipment, such as advanced medical imaging equipment (e.g., computed tomography (Cat Scans) and magnetic resonance imaging ; (2) implantable devices such as cardiac pacemakers and orthopedic implants; (3) non-implantable devices, such as ventilators, infusion pumps, surgical supplies, and diagnostic test kits. Of course, all products entering the U.S. market must have FDA approval and from facilities that must be subjected to FDA inspections.

We provide this analysis because we want USG officials to understand that we are not underestimating the competitiveness of the Chinese industry or the potential threat from the power and resources of the Chinese government. We have voiced our concerns about Chinese policies, including about "Made in China: 2025," which sets the goals of

increasing the use of domestic high-end medical devices in county hospitals to 70% by 2025, and the percentage of domestic content in core components by up to 80% by 2025. While "Made in China: 2025" was highlighted in the Section 301 Report, there was no mention of the specific measures China might use to meet these broad goals for our industry. Imposing higher tariffs on medical technology imports from China will not help U.S. competitiveness or achieve the President's objectives for our industry.

Inconsistent with Public Health

Including medical technology products on the USTR list is troubling from a public health perspective. Healthcare products have been consistently recognized as being exempt from trade sanctions – even with countries which the United States considers to be security risks. For example, the Trade Sanctions Reform and Export Enhancement Act of 2000 and all subsequent sanctions legislation, embargoes, and policy disputes with other countries to date, have indicated that key humanitarian products, including medical devices, should be excluded from such trade measures. The fundamental rationale is that patients should have access to basic human necessities. Therefore, we believe medical technology should be exempted from USTR's Section 301 lists for humanitarian reasons alone.

We are also concerned that the import tax of medical technology could be disruptive to patient access in some areas, especially if the tariff were to be imposed for a lengthy period. When a 25 percent tax is introduced into a market, those costs have to be absorbed somewhere − by the manufacturer, the distributor, the customer (hospital/lab) or the patient. In the U.S. healthcare market – with payments for medical technology largely coming indirectly from insurance companies, Medicare, and out-of-pocket patient expenses – manufacturers have very limited ability to pass on cost increases. (That is, hospitals purchase the medical technology from the manufacturers or distributors, and the hospitals are reimbursed for procedures involving medical devices and diagnostics by private parties or the government.)

While it is not possible for us to forecast the precise balance of these forces, a 25 percent tax puts pressure on the system and could force the industry to cut costs to compensate in areas such as R&D and jobs. Steadily declining Medicare reimbursement rates already are causing razor-thin margins for some manufacturers; an additional tax makes it even more difficult, if not completely untenable, to continue to supply these products. Absent an ability to absorb these costs, there will pressures to reduce supplies.

AdvaMed Involvement in China

AdvaMed has been deeply engaged in China since 2005, when we began collaboration with the Chinese Government on a variety of regulatory, ethical business practices, and payment issues. We first hired a part-time employee in 2007. We now have an office in Shanghai and a subsidiary in Beijing. We expect to expand to a staff of 7-8 by the end of this year. Of course, some of our members have been selling medical devices and diagnostics in China for several decades and have developed their own relationships with Chinese officials and other stakeholders.

During the period in which AdvaMed has been intensely engaged on Chinese policies, we have experienced challenges, frustrations, failures and successes – with several of those achievements coming under the Trump Administration. We will not catalogue these issues in this testimony – as we have been fortunate to enjoy the support of USG agencies − such as USTR, Commerce, State, Treasury, and the U.S. Embassy – and have documented these areas over the years. We greatly appreciate this assistance and believe USG involvement has been directly responsible for whatever successes we have experienced. However, we remain concerned that USTR actions and Chinese reactions could undermine our mutual progress for industry and patients alike.

Chinese Retaliation

China's response to USTR tariff lists has been to impose tariffs on all of its imports of U.S. medical technology – as best we can determine. However, because of the aggregate nature of the HTS and lack of harmonization between the US and Chinese HTS codes, we cannot verify the exact value of these U.S. exports to China. The impact, however, is not insubstantial given the size and growth of the Chinese market for medical devices and the fact that the United States is the leading supplier of medical devices to the China market.

Chinese patients will continue to have access to innovative medical technology, but from other sources. The U.S. industry is the leading supplier to China -- accounting for over 30 percent of its medical device and diagnostic imports. China will look for countries outside the United States – Europe, Japan, Southeast Asia – as alternative sources for U.S. technologies. A series of tit-for-tat retaliatory tariffs that lasts a prolong period would adversely impact our industry in the United States and their business with China.

The Chinese government has greater legal flexibility in imposing non-tariff barriers and restrictions than does the USG. The Chinese regulatory authority must approve all foreign medical devices and diagnostics for safety and effectiveness – just as USFDA does in the United States. Central government officials can influence the timing of regulatory approval decisions for U.S. medical devices, delaying market access. Likewise, public hospitals, operated by some level of government authority (central, provincial, city) are responsible for over 80 percent of healthcare delivery in China. These government authorities can impose limitations on the amount of U.S. medical devices and diagnostics purchased.

In addition to these potential Chinese actions that could directly target U.S. medical technology, the Chinese Government has additional tools to foster a hostile environment in China. For example, Chinese authorities could launch investigations under its anti-monopoly laws, its anti-corruption laws, or its new cybersecurity laws. Even if no violation were found, the investigations themselves are chilling, costly and undermine U.S. business confidence.

Section 301 Investigation and Report

Investigation

AdvaMed and our members chose not to participate in the Section 301 investigation, which was focused on intellectual property (IP) theft and forced technology transfers. While these issues are of some concern to our members, they are not the primary obstacles we face in accessing the Chinese market.

USTR Report

We applaud the lengthy and detailed Section 301 report USTR issued on March 22, 2018. However, the medical technology industry is not cited in the 182-page document.

Alternative Approach

AdvaMed and our members do not endorse imposing import tariffs on medical technology as a means of changing China's behavior in our industry. Indeed, we believe that these tariffs could undermine our efforts to obtain and maintain access to China's market on a mutually reciprocal basis, as well as impact our global competitiveness.

AdvaMed has laid out clear issues in the regulatory and payment areas that need to be addressed by China for our industry to obtain access to the Chinese market comparable to the access that the Chinese medical technology industry enjoys in the United States. For example:

- Clinical trial requirements imposed based on international best practices;
- UDI system based on international standards;
- End of country-of-origin requirements;
- Continued postponement of national pricing system for medical technology;
- Implementation of two-invoice systems only if appropriate for medical technology;
- Central tendering systems that do not disadvantage U.S. firms.

If a final agreement is reached between U.S. and Chinese negotiators, we will be evaluating its benefits on the basis of progress reached in these areas. We realize that implementation must be secured, that additional progress must be made, that we need strong USG support. We also recognize that strong enforcement provisions must be included to discourage China from reverting to behavior that adversely affects our industry.

Conclusion and Requests

Our industry will be less competitive if import tariffs remained on the products we identified above. We respectfully request that increased tariffs on imports of the medical technology products be removed and no additional tariffs be imposed.

Annex 1

Medical Devices on $34 billion US List

8419.90.50.40	8419.90.50.40 - Parts Of Medical, Surgical or Laboratory Sterilize
*8421.91.60	8421.91.60 - Parts of centrifuges, including centrifugal dryers, nesoi
*9011.80.00	90118000 – Compound optical microscopes other than stereoscopic or those for microphotography, microcinematography or microprojection
9018.11.30	9018.11.30 - Electrocardiographs
9018.11.60	9018.11.60 - Printed Circuit Assemblies For Electrocardiographs
9018.11.90	9018.11.90 - Parts and Accessories For Electrocardiographs,Neso
9018.12	9018.12 - Ultrasonic Scanning Apparatus
9018.13	9018.13 - Magnetic Resonance Imaging Apparatus
9018.14	9018.14 - Scintigraphic Apparatus
9018.19.40	9018.19.40 - Apparatus, Functional Exploratory Examination& Pts
9018.19.55	9018.19.55 - Patient Monitoring Systems
9018.19.75	9018.19.75 - Printd Circ Assemb For Parameter Acquisition Modul
9018.19.95	Electro-diagnostic apparatus nesi, and parts and accessories thereof nesi Ultraviolet or infrared ray apparatus used in medical, surgical, dental or veterinary sciences, and parts and accessories thereof
9018.20	9018.2 - Ultraviolet or Infrared Ray Apparatus, & Pts & Acc
9018.90.20	9018.90.20 - Optical Instruments and Appliances and Parts,Nesoi
9018.90.30	9018.90.30 - Anesthetic Instruments and Appliances and Parts
9018.90.60	9018.90.60 - Electro-Surgical Instruments & Appliances & Parts
9018.90.75	9018.90.75 - Dialysis Instruments and Apparatus
9021.50	9021.5 - Pacemakers For Stimulating Heart Muscles
9022.12	9022.12 - Computed Tomography Apparatus
9022.13	9022.13 - Appts Base On X-Ray For Dental, Uses, Nesoi
9022.14	9022.14 - Appts Base On X-Ray, Medical,Surgical,Vetnry,Nesoi
9022.21	9022.21 - Appts Base On Alpha,Beta,Etc. Radiation,Medical,Etc.
9022.30	9022.3 - X-Ray Tubes
9022.90.05	9022.90.05 - Radiation Generator Units
9022.90.15	9022.90.15 - Radiation Beam Delivery Units
9022.90.25	9022.90.25 - High Tension Generators,Desks,Chair,Etc.
9022.90.40	9022.90.40 - Parts and Accessories Of X-Ray Tubes
9022.90.60	9022.90.60 - Pts Of Apparatus Based On The Use Of X-Rays
9022.90.95	9022.90.95 - Pts,Use Alpha,Beta/Gamma Radiations, Etc., Nesoi
*9027.50.40	9027.50.40Electrical instruments and apparatus using optical radiations (ultraviolet, visible, infrared), nesoi

*9027.80.45	9027.80.45- Electrical instruments and apparatus for physical or chemical analysis, measuring viscosity, checking heat, sound, light, etc, nesoi
*9027.90.56	9027.90.56 - Parts and accessories of electrical instruments and apparatus of subheading 902720, 902730, 902750 or 902780
*9027.90.59	Other parts and accessories of other electrical instruments and apparatus of heading 9027, nesoi
*9030.33.38	9030.33.38 Other instruments and apparatus, nesoi, for measuring or checking electrical voltage, current, resistance or power, without a recording device

*Not previously included as medical device due to classification error

Annex 2

List of Medical Devices on USTR's $16 Billion Section 301 List

9025.19.80
- 9025.19.80.40 Clinical thermometer, nt combined w/oth inst,nesoi
- 9025.19.80.80 Thermometers, nt combined with oth inst

9029.20.40
- 9029.20.40.40 Speedometers & tachometers used in civil aircraft
- 9029.20.40.80 Speedometers, tachometers nt for civ aircrft nesoi

3919.90.50
- 3919.90.50.10 Self-adhesive reflectorized sheeting of plastics
- 3919.90.50.20 Filament reinforced tape, in rolls exceeding 20 cm
- 3919.90.50.12 Electrical tape, in rolls exceeding 20 cm wide
- 3919.90.50.30 Transparent tape, in rolls exceeding 20 cm wide
- 3919.90.50.60 Self-adhs plate,sheet,strip,etc of plastics,nesoi

3917.40.00
- 3917.40.00.10 Fittings for vehicle brake hoses
- 3917.40.00.90 Other fittings for tubes,pipes & hoses,of plastic

3920.10.00 Nonadhesive plates, sheets, film, foil and strip, noncellular, not reinforced or combined with other materials, of polymers of ethylene

9030.84.00 Instruments & apparatus with .recordng device nesoi

9030.89.01 Instruments & apparatus w/o recording device nesoi

Annex 3

Medical Technology HTS Categories on USTR List 4

*3926.90.99.10	Laboratory Ware
*3926.90.99.90	Plastic parts of medical devices
4015.19	Gloves, Except surgical, Vulcan rubber, nesoi
6115.10	Graduated compression hosiery
6307.90.60	Perineal towels of fabric formed on base of paper
*6307.90.68	Surgical Drapes, Disp, Spunlaced/Bonded, Man-Made
6307.90.89	Cotton Surgical Towels
*8528.52.0000	Monitors for used in or with diagnostics and medical devices
9001.30	Contact lenses
*9027.90.2000	Microtomes

*Not previously included as medical device due to classification error

Annex 4

List of Non-Medical Device Inputs for Manufacturing Medical Devices in the U.S.

38089410 – Disinfectants, containing any aromatic or modified aromatic disinfectant

40169915 - Caps, lids, seals, stoppers and other closures, of noncellular vulcanized rubber other than hard rubber

73181600 - Iron or steel, nuts

73202050 - Iron or steel, helical springs (o/than suitable for motor vehicle suspension)

76061260 - Aluminum alloy, plates/sheets/strip, w/thick. o/0.2mm, rectangular (incl. sq), clad

76082000 - Aluminum alloy, tubes and pipes

84135000 - Reciprocating positive displacement pumps for liquids, not fitted with a measuring device, nesi

84136000 - Rotary positive displacement pumps for liquids, not fitted with a measuring device, nesi

84137020 - Centrifugal pumps for liquids, not fitted with a measuring device, nesi

84138100 - Pumps for liquids, not fitted with a measuring device, nesi

84139190 - Parts of pumps, nesi

84149090 - Parts of air or vacuum pumps and ventilating or recycling hoods

84186901 - Refrigerating or freezing equipment nes

84199050 - Parts of molten salt cooled acrylic acid reactors, nesi; parts of certain medical, surgical or laboratory sterilizers, nes

84199095 - Parts of machinery, plant or laboratory equipment for the treatment of materials by a process involving a change of temperature, nesoi

84213980 - Filtering or purifying machinery and apparatus for gases, other than intake air filters for internal combustion engines or catalytic conv.

84239090 - Other parts of weighing machinery, including weights

84283900 – Continuous action elevators and conveyors, for goods or materials, nesi

84289002 - Machinery for lifting, handling, loading or unloading, nesi

84313900 - Parts suitable for use solely or principally with the machinery of heading 8428, nes

84433250 - Single function units other than printer units (machines which perform only one of the functions of printing, copying or facsimile transmiss

84439925 - Parts and accessories of printers, neso

85361000 - Fuses, for a voltage not exceeding 1,000 V

84602400 - Other grinding machines, numerically controlled
84661001 - Tool holders and self-opening dieheads for use solely or principally with machines of headings 8456 to 8465, nesoi
84662010 - Work holders for machine tools used in cutting gears
84662080 - Work holders for machine tools other than those used in cutting gears, nesoi
84716080 - Optical scanners and magnetic ink recognition devices not entered with the rest of a ADP system
84717040 - ADP magnetic disk drive storage units, disk dia. n/ov 21 cm,not in cabinet, w/o attached external power supply, n/entered w/rest of a system
84717060 - ADP storage units other than magnetic disk, not in cabinetsfor placing on a table, etc., not entered with the rest of a system
84717090 - ADP storage units other than magnetic disk drive units, nesoi, not entered with the rest of a system
84779085 - Parts of machinery for working rubber or plastics or for the manufacture of products from these materials, neso
84798200 - Machines for mixing, kneading, crushing, grinding, screening, sifting, homogenizing, emulsifying or stirring, nesi
84799094 - Parts of machines and mechanical appliances having individual functions, not specified or included elsewhere in chapter 84, neso
84807180 - Molds for rubber or plastics, injection or compression types, other than for shoe machinery or for manufacture of semiconductor devices
84819090 - Parts of taps, cocks, valves and similar appliances for pipes, boiler shells, tanks, vats or the like, nes
84821050 - Ball bearings other than ball bearings with integral shafts
84829965 - Parts of other ball or roller bearings, nesi
84839080 - Parts of transmission equipment, nesi
85011040 - Electric motors of an output of under 18.65 W, other than synchronous valued not over $4 each
85013120 - DC motors nesi, of an output exceeding 37.5 W but not exceeding 74.6 W
85030075 - Parts of electric motors under 18.65 W, other than commutators, stators or rotors
85043200 - Electrical transformers other than liquid dielectric, having a power handling capacity exceeding 1 kVA but not exceeding 16 kVA
85044040 - Electrical speed drive controllers for electric motors (static converters)

85049041 - Parts of power supplies (other than printed circuit assemblies) for automatic data processing machines or units thereof of heading 8471

85049065 - Printed circuit assemblies of the goods of subheading 8504.40 or 8504.50 for telecommunication apparatus

85049075 - Printed circuit assemblies of electrical transformers, static converters and inductors, nesoi

85049096 - Parts (other than printed circuit assemblies) of electrical transformers, static converters and inductors

85065000 - Lithium primary cells and primary batteries

85059075 - Other electromagnets and parts thereof, and parts of related electromagnetic articles nesi

8517.62.0900 – Machines for reception, conversion, and transmission or regeneration of voice images or other data, nesoi 8517.62.0090

85238020 - Discs, tapes, solid state non volatile storage devices, "smart cards" and other media for the recording of sound or of other phenomena, whet

85285933 - Color video monitors w/flat panel screen, video display diagonal > 34.29 cm, not with VCR/player, not subj US note 13

85299022 - Other printed circuit assemblies suitable for use solely or principally with the apparatus of headings 8525 to 8528, nesi

85299083 - Other parts of television apparatus (other than television cameras), nesi

85322300 - Ceramic dielectric fixed capacitors, single layer

85322900 - Fixed electrical capacitors, nesi

85334080 - Electrical variable resistors, other than wirewound, including rheostats and Potentiometers

85361000 - Fuses, for a voltage not exceeding 1,000 V

85362000 - Automatic circuit breakers, for a voltage not exceeding 1,000 V

85364900 - Relays for switching, protecting or making connections to or in electrical circuits, for a voltage exceeding 60 but not exceeding 1,000 V

85365090 - Switches nesoi, for switching or making connections to or in electrical circuits, for a voltage not exceeding 1,000 V

85369040 - Electrical terminals, electrical splicers and electrical couplings, wafer probers, for a voltage not exceeding 1,000 V

85369085 - Other electrical apparatus nesi, for switching or making connections to or in electrical circuits, for a voltage not exceeding 1,000 V, nesoi
85389060 - Molded parts nesi, suitable for use solely or principally with the apparatus of heading 8535, 8536 or 8537
85389081 - Other parts nesi, suitable for use solely or principally with the apparatus of heading 8535, 8536 or 8537
85414020 - Light-emitting diodes (LED's)
85414070 - Photosensitive transistors
85414080 - Photosensitive semiconductor devices nesi, optical coupled isolators
85444990 - Insulated electric conductors nesi, not of copper, for a voltage not exceeding 1,000 V, not fitted with connectors
85447000 - Optical fiber cables made up of individually sheathed fibers
90029095 - Mounted optical elements, nesi; parts and accessories of mounted optical elements, nesi
90132000 - Lasers, other than laser diodes
90138070 - Liquid crystal and other optical flat panel displays other than for articles of heading 8528, nesoi
90258015 - Nonelectrical barometers, not combined with other instruments
90258040 - Thermographs, barographs, hygrographs and other recording instruments, other than electrical
90258050 - Combinations of thermometers, barometers and similar temperature and atmosphere measuring and recording instruments, nonelectrical
90262080 - Instruments and apparatus, other than electrical, for measuring or checking the pressure of liquids or gases
90278025 - Nuclear magnetic resonance instruments
90278045 - Electrical instruments and apparatus for physical or chemical analysis, measuring viscosity, checking heat, sound, light, etc., nesi
90279045 - Printed circuit assemblies for instruments and apparatus of subheading 9027.80
90279054 - Parts and accessories of electrophoresis instruments not incorporating an optical or other measuring device
90279056 - Parts and accessories of electrical instruments and apparatus of subheading 9027.20, 9027.30, 9027.50 or 9027.80

90308200 - Instruments and apparatus for measuring or checking electrical quantities, nesoi: for measuring or checking semiconductor wafers or devices

90318080 - Measuring and checking instruments, appliances and machines, nes

90319091 - Parts and accessories of measuring or checking instruments, appliances and machines, nesoi

90321000 - Automatic thermostats

90328960 - Automatic regulating or controlling instruments and apparatus, nesi